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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
TAYLOR ET AL.
APPLICATION NO: Herewith
FILED: Herewith
FOR: LIPOSOMAL INTERFERON HYBRID COMPOSITION

Art Unit:
Examiner:

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above-referenced patent application, please amend the application as follows:

In the Specification:

Please insert the following after the title, page 1:

-- This application is a continuation of Application 09/257,446, which is a 371 of PCT/GB95/02821, filed April 12, 1995, which in its entirety is herein incorporated by reference.--

In the Claims:

Cancel Claims 1-21 and add new Claims 22-34 as follows:

22. A pharmaceutical composition for treating a viral liver disease comprising an α-interferon B/D hybrid contained in liposomes formed from a lipid mixture having a phase transition temperature of 20°C to 30°C wherein the lipid mixture comprises 50 to 75 mol % of

a neutral phospholipid, 20 to 40 mol % of cholesterol and 5 to 10 mol % of a negatively charged phospholipid.

23. The composition according to Claim 22 wherein the α-interferon B/D hybrid is a α-interferon BDBB hybrid.

24. The composition according to Claim 22 wherein the neutral phospholipid component comprises at least one phosphatidylcholines.

25. The composition according to Claim 22 wherein the neutral phospholipid component is dimyristoyl phosphatidylcholine or a mixture of dimyristoyl phosphatidylcholine with another neutral phosphatidylcholine.

26. The composition according to Claim 22 wherein the negatively charged phospholipid component comprises at least one phosphatidylserine.

27. The composition according to Claim 22 wherein the negatively charged phospholipid component is dioleoyl phosphatidylserine.

28. The composition according to Claim 22 wherein the lipid mixture comprises 55 to 70 mol % neutral phospholipid, 25 to 36 mol % cholesterol and 5 to 10 mol % negatively charged phospholipid.

29. The composition according to Claim 22 wherein the molar ratio of neutral phospholipid: cholesterol: charged phospholipid is 9:5:1.

30. The composition according to Claim 22 wherein the liposomes have an average particle size up to 200 nanometers.

31. The composition according to Claim 30 wherein the liposomes have an average particle size of 80 to 180 nm.

32. The composition according to Claim 22 wherein the weight ratio of the α-interferon B/D hybrid to the lipid mixture is from 1:400 to 1:300.

33. The composition according to Claim 22 wherein the liposomes are in dehydrated form.

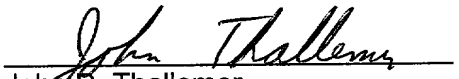
34. A method of preparing a composition according to Claim 22 comprising removing solvent from a solution of the lipid mixture in an organic solvent to give a lipid residue, mixing the lipid residue with an aqueous medium containing an α-interferon hybrid, agitating the resulting mixture to obtain an aqueous suspension of liposomes containing entrapped α-interferon hybrid and extruding the suspension through one or more membrane filters.

REMARKS

By this Preliminary Amendment, applicants have cancelled Claims 1-21and added new Claims 22-34. Support for new Claims 22-34 is found in the cancelled claims. More specifically, applicants have included a phase transition temperature limitation for the lipid mixture, as found in the specification on page 2, lines 8-9, and specified that the charged phospholipid be negatively charged, as found in the specification on page 3, line 1.

Applicants respectfully request that the Examiner enter applicants' Preliminary Amendment.

Respectfully submitted,



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